

Appl. No. 10/681,639  
Amendment dated October 1, 2008  
Reply to Advisory Action

### REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of the above-identified application in view of the foregoing remarks.

Claims 1, 2, 5-7, 10-13, 20, 21, 24-26, and 33-39 stand in the application.

#### Claim Rejections – 35 USC 103

Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33, and 34 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500). The Examiner has asserted in the Advisory Action dated August 5, 2008 that the arguments submitted by the Applicant in response to the most recent Official Action are not persuasive. The Applicant respectfully disagrees with the Examiner.

The Examiner has noted in the Advisory Action that the rejected claims do not exclude the presence of a porous membrane in the platform flow channel upstream of the membrane as taught in the '041 patent. The Examiner's assertion is incorrect. The '041 patent recites an assay device comprising a series of connected membranes, in which a liquid sample is introduced directly to an upstream porous reservoir pad and then migrates through a filter membrane into a detection membrane (see col 3, lines 27-29; col 3, lines 62-67; and col 4, lines 1-3). In contrast, the claimed invention recites a flow channel upstream of the membrane to receive a small volume of sample. A "channel" is understood by one skilled in the art that the flow channel is empty and does not encompass such an embodiment and the claimed device would not work as described. It is further noted that claim 1 recites that the channel is in fluid communication with the membrane to permit the liquid sample to flow in a continuous pathway from the sample application means to the distal end of the membrane. The channel also functions to regulate the volume of the applied sample. This is more clearly seen on the Applicants'

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\_\_\_\_\_ demonstrates how the claimed platform functions and the structural features of the channel. This video very explicitly shows that the channel regulates the small sample volume and the flow of the sample to the membrane. One can clearly see how much sample to apply in the channel as it flows rapidly therethrough. This channel functions to help regulate the small volume. If a membrane was present in the channel not only would it adversely affect the sample volume but also retard the sample flow and the platform would not work efficiently. The claimed platform is therefore clearly very different to that taught in the '041 patent. Also attached hereto is a description of the claimed platform and its advantages as is printed from the Applicants' website ([www.zbx.ca](http://www.zbx.ca)).

With regards to the Applicant's previous arguments, the Examiner has asserted that the device of the '041 is not excluded from being capable for use with small volumes on the order of 110  $\mu$ L (Examples 4 to 16) and 200  $\mu$ L (Examples 18 to 20). In contrast, the device of the present application is designed to detect analytes in sample volumes as small as 35  $\mu$ L (see paragraphs 33 and 35). The sample volumes of the platform of the subject application that is capable of detecting analytes in liquid samples of very small volume.

The '619 patent and the '500 patent relied upon by the Examiner do respectively teach a container holding membranes, and the hydrophilic treatment of the container with the teachings of the '619 and '500 patents to arrive at the unobvious invention claimed.

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None of cited prior art teaches or suggests combination to all of the elements recited in each of the independent claims and therefore cannot render the claims obvious.

Should the examiner wish to discuss the foregoing amendments to the claims, applicants would appreciate a telephone call to their undersigned representative.

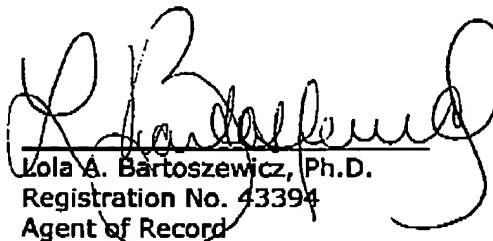
Conclusion

The Applicant requests the Examiner reconsider and withdraw all outstanding objections and rejections, enter the amendments, and pass the resulting claims to allowance.

Respectfully Submitted,  
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LAB/ca

Encls.

  
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# THE ZBX CORPORATION ANALYTICAL PLATFORM



## QUICK AND EASY DETECTION WITH ONLY ONE DROP OF WHOLE BLOOD

### READABILITY FEATURES

- Automatic test processes can be seen and test condition can be visually verified
- Test system inhibits further development after results are readable
- Well-suited for busy testing sites
- Easily adapted to reader technologies

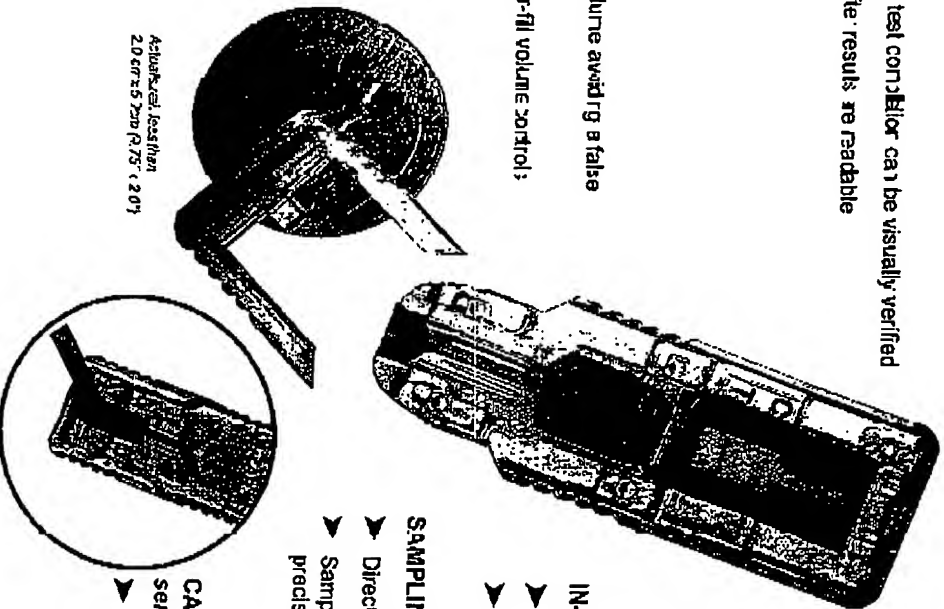
### BUILT-IN VOLUME CONTROL

- Test initiates only with adequate sample volume avoiding a false negative
- Test system incorporates under-fill and over-fill volume control; increasing reliability of results

### CAP REMOVED - For application of capillary blood sample from finger stick

- The cap is simply removed to enable capillary blood sample from finger stick. If desired, the cap can be easily reattached for safety and ease of handling

Adjustable length  
2.0 cm to 7.20 cm (0.75" to 2.87")



### SMALL SAMPLE VOLUME

- About 35µl of capillary blood or venous blood, plasma or serum

### POSITIVE CONTROL

- Built-in positive control assures that user that the system is performing to specification

### IN-LINE PLASMA SEPARATION

- No sample preparation required for whole blood samples
- Eliminates need for centrifugation

### SAMPLING FLEXIBILITY

- Direct finger stick (capillary) sampling requires no sample transfer device
- Sampling for venous blood, plasma or serum requires a transfer device but precise volume in the transfer device is not critical

### CAP ATTACHED (inset left) - For application of whole blood, serum or plasma sample from a transfer device

- The cap attached to the analytical platform easily guides the pipette tip or other sample transfer device